

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE OF ALTERNATIVE MEDICINE

ALTERNATIVE MEDICINE PROGRAM ADVISORY COUNCIL
SUMMARY MINUTES OF MEETING

February 10-11, 1997

Bethesda, Maryland

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
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SUMMARY MINUTES OF MEETING
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The Alternative Medicine Program Advisory Council (AMPAC) of the Office of Alternative Medicine (OAM) convened for its eighth meeting at 8:30 a.m.* on February 10-11, 1997 in the Versailles II Room of the Holiday Inn at 8120 Wisconsin Avenue in Bethesda, Maryland. Dr. James S. Gordon presided as Chair. The meeting was open to the public.

*All times are approximate.

AMPAC MEMBERS PRESENT

The Honorable Berkely Bedell
Dr. Brian M. Berman
Ms. Carola Burroughs
Dr. Barrie Cassileth
Dr. David M. Eisenberg
Dr. Noreen Cavan Frisch
Dr. James S. Gordon
Mrs. M. Linden Griffith
Mr. Gar Hildenbrand
Sister Charlotte Kerr
Dr. Ralph Moss
Mrs. Carolene Marks
Dr. Lorenz K. Y. Ng
Dr. Richard S. Panush
Dr. Beverly Rubik
Ms. Ellen Silverstone
Dr. Robert Temple (Ex Officio)

OAM STAFF PRESENT

Paul Burke
Dr. Cheong C. Chah, Program Officer (NINR)
Dr. Li-Chuan Chen, IRTA Fellow
Dr. Geoffrey P. Cheung, Executive Secretary, AMPAC
Dr. Ronald Chez
Ms. Anita Greene, Program Officer
CAPT Nancy Hazleton, Program Officer
Dr. Carole Hudgings, Program Officer
Dr. Wayne B. Jonas, Director (Ex Officio)

Dr. Richard L. Nahin, Program Officer
Ms. Ann Scheppach, Senior Advisor for Legislative and Strategic Planning
Dr. Jeffrey White

STAFF OF OTHER NIH COMPONENTS PRESENT

Dr. Paul Coates, NIDDK
Dr. Jerome Cott, NIMH
Dr. William Harlan, ODP/OD
Angela Magliozzi, OD
Dr. Bernadette Marriott, ODS
Ms. Judy Murphy, NIAID
Julian Pruder, CDC
Ms. Anna Snouffer, CMO/OD
Susana Sztein, NIAMS
Dr. Alan I. Trachtenberg, NIDA

OTHERS PRESENT

Ms. Kelley Long Gillespie, Ms. Nadine Jackson, Courtesy Associates
Ms. Melanie Kobrin

MEDIA PRESENT

D.H. Brinkley, Harper Collins
Paul Caems, *Self Magazine*
Susan Easton, *"The Tam Sheet"*
Michael Eyers, *Natural HealthLine*
Betsy Herrick, *Micromedia*
Alice Ortuzar, Well Mind Assoc. of Greater Washington
Georgia J. Persinos, Ph.D., *Washington Insight*
Rupert Shephard, *FDC Reports*
Jack Thomas, *Touch Therapy Times*
Michael Villaire, Innovisions Communications
Rick Weiss, *The Washington Post*
Alice Wahl, MA, CHES, *Middle Age Times*
K. White, V.R. Studio
J. Wootton, JACM

MEMBERS OF THE PUBLIC PRESENT

Ms. Nagisa Bianchin, Johnson & Johnson (Skillman, NJ)
Ms. Lee Bechtel, American Assoc. of Naturopathic Physicians (Silver Spring, MD)
Dr. Barbara Brewitt, Chief Scientist, Bastyr University AIDS Research Center (Seattle, WA)
Mr. Dammion Brinkley (Aiken, SC)
Ms. Martha Burke, Music Therapist, Durham, NC)
Dr. David Chung, Howard University (Wash., DC)
Ms. Susan Dziemia, Englewood Hospital (Englewood, NJ)

Dr. Daniel Eskinazi, The Richard and Hinda Rosenthal Center for Complementary and Alternative Medicine, Columbia University (New York, NY)

Ms. Tracy Fox, American Dietetic Association (Washington, DC)

Mr. Jeff Franklin (Ashton, MD)

Mrs. Christeene Hildenbrand, Vice-President and Director, Gerson Research Organization (San Diego, CA)

Dr. Feifei Hoag, Acupuncturist (Bethesda, MD)

Ms. Freddie Ann Hoffman, FDA (Washington, DC)

Ms. Lindsay Jones, Alliance for Healing Arts & Sciences (Flat Rock, NC)

Dr. Peter Klein, Montgomery Mental Health (Bethesda, MD)

Dr. Hope Kellman, Research Director, Health Technologies (Silver Spring, MD)

Dr. Fredi Kronenberg, Principal Investigator, Center for CAM Research in Women's Health, College of Physicians & Surgeons, Columbia University (New York, NY)

Dr. F.LeVerf, Karmans Cancer Institute, Wayne State University (IN)

Dr. J. William LaValley (Austin, TX and Chester, Nova Scotia, Canada)

Ms. Marsha Marks (Bethesda, MD)

Ms. Barbara Mayerman (Arnold, MD)

Ms. Karen Meengs, Attorney, Over the Cliff (Great Falls, VA)

Ms. Jennifer Reck, student, Cornell University (Ithaca, NY)

Mr. Everett Rhoades, Assoc. Dean, University of Oklahoma College of Medicine (Oklahoma City, OK)

Ms. Mary Ann Richardson, (VA)

Mr. Maury Silverman (Silver Spring, MD)

Mr. Robert Spiegel, Psycho-Medical Chirologists (Silver Spring, MD)

Mr. David Vinjamin, Advanced Care Products (Skillman, NJ)

I. CALL TO ORDER AND OPENING REMARKS

Dr. Geoffrey P. Cheung, Executive Secretary, AMPAC and Dr. Wayne B. Jonas, Director, OAM

Dr. Cheung opened the eighth meeting of the AMPAC. Drs. Jonas and Gordon welcomed attendees/6,23. Dr. Cheung extended a special welcome to Dr. Robert Temple, a new nonvoting [ex-officio] Council member serving as FDA liaison to the AMPAC; and to Dr. Ronald Chez, on sabbatical to the OAM from the University of South Florida/5-6. Dr. Cheung recognized the following NIH staff: Ms. Anna Snouffer, CMO/OD; Ms. Judy Murphy, NIAID; Dr. Paul Coates, NIDDK; and Dr. Jerome Cott, NIMH.

CONFIRM THAT NO OTHER MEMBERS NEED TO BE ADDED.

II. REMARKS OF THE ASSOCIATE DIRECTOR, ODP/OD

Dr. William Harlan, Associate Director, ODP/OD

The OAM has moved in a very impressive direction under Dr. Jonas' leadership during the last 6 months since the completion of structural shifts undertaken as part of the NIH-wide restructuring/9.

Drs. Jonas and Cheung have met with approximately three-quarters of the ICD directors to discuss OAM goals, activities, and CAM-related efforts in which ICDs already are engaged part of their grant portfolios/9. ICD directors have expressed great interest in working with the OAM/10. In addition to producing shorter-term benefits such as new projects, these meetings yield tremendous long-term dividends by fostering cooperative relationships to support future efforts/11. By collaborating with the ICDs, the OAM can leverage a small amount of funding in a particular research area against the ICDs' more substantial financial and personnel resources/10-11.

A discussion followed Dr. Harlan's remarks. Mr. Berkely Bedell stated that the OAM is mandated to investigate and validate alternative treatments, but currently is not conducting such investigations except through the CAM Research Centers/16. He solicited feedback regarding concerns that the transfer of the OAM to the ODP may represent a downgrading of the OAM's position within the NIH, that the departure of many of Council's more outspoken members could suggest an attempt by the NIH to remove sources of dissension, and that AMPAC perspectives may not be heard at the highest levels of the NIH/19-20. Dr. Harlan stated that all NIH advisory committees require members to rotate off after completing a period of service that cannot be exceeded/18. (The topics of practice assessments, Council nominations, and mechanisms through which the NIH listens to the advice of its advisory councils are addressed in other sections of the minutes.)

Mr. Gar Hildenbrand noted the lack of continuity created by eight members rotating off Council simultaneously, and expressed concern about the tendency of bureaucratic systems to acculturate new members/20-21. He asked that the minutes reflect his agreement with Mr. Bedell's comments and his belief in the urgent need for rapid action by the OAM to investigate and validate CAM treatments for currently fatal diseases/22. Dr. Cheung stated that Mr. Bedell's and Mr. Hildenbrand's comments would be reflected in the minutes/22.

III. PRESENTATION AND DISCUSSION: ODS DIRECTOR'S REPORT **Dr. Bernadette Marriott, Director, ODS**

The ODS was established by Congress through the Dietary Supplement Health and Education Act (DSHEA) of 1994, which

amended the Federal Food, Drug and Cosmetic Act and set standards and a broader definition for dietary supplements/25-26. The ODS is a trans-NIH coordinating office located in the OD, and will work closely with other OD offices; the OAM, the Office of Medical Applications of Research (OMAR), the Office of Rare Diseases, and the Women's Health Initiative of the Office of Research on Women's Health have interests and areas of activity that overlap with those of the ODS/28. Drs. Marriott and Jonas have met regularly since Dr. Marriott's arrival at the NIH approximately one year ago/25.

Mandated tasks of the ODS include promotion of scientific study on dietary supplements, creation of databases, coordination of funding for research on dietary supplements at the NIH, and provision of advice to agencies within HHS/27. To identify opportunities for collaboration and to cofund new initiatives, the ODS is meeting with the ICDs and working with HHS components other than the NIH/30.

The ODS has held six strategic planning meetings involving 83 experts in diverse disciplines and drafted a 5-year strategic plan that will be finalized after input is obtained from NIH components and other HHS agencies/31-32,43. The ODS has cosponsored conferences and a major workshop with ICDs, the American Institute of Nutrition, and the American Society for Clinical Nutrition/32. Topics have included genetic and environmental determinants of copper requirements, melatonin, and the role of dietary supplements for physically active individuals/32.

In 1996, the ODS funded six grants through the Research Enhancement Awards Program (REAP): (1) Antibiotic-induced hearing loss with the NINDDS, (2) vanadium salts and carbohydrate metabolism in humans, (3) triptophan and Native American alcoholism, (4) brain MR spectroscopic studies of thiamine deficiency, (5) mechanisms of anti-folate efficacy in arthritis, and (6) bone density loss in athletes/35-36. The ODS also has established a gift fund through which partnerships can be formed with private industry and foundations to support NIH-approved research/39.

Work has begun on two databases that will be available on the World Wide Web: Computer Access to Research on Dietary Supplements (CARDS), and International Bibliographic Information on Dietary Supplements (IBDS)/36-39.

In 1997, the ODS will continue activities related to REAP and database development, formally assess the need for a public information center on dietary supplements, explore the feasibility of maintaining the NHNES dietary supplement

products database, and participate in the design of questions for the expanded dietary supplement module of the next National Health and Nutrition Examination Survey (NHNES)/39-41. The ODS also will cosponsor two international workshops on nutrient supplements and brain function, and on advances in botanical supplement research"/65.

A discussion followed Dr. Marriott's presentation. Dr. Marriott noted that the ODS is interested not only in single botanicals, but also in mixed botanicals, botanicals added to foods, and alternative dietary supplements combining multiple ingredients/46-47. She indicated her willingness to meet with Ms. Carola Burroughs to discuss research needs involving dietary supplements and AIDS/48. ODS operating principles are likely to include a focus on more comprehensive studies and to reflect a strong interest in safety and toxicity/51-53. Many opportunities for large studies exist internationally as well as nationally/50. The ODS will form partnerships to pursue such efforts because of their cost and the size of the ODS budget/50. The ODS will collaborate with the ICDs to identify research topics of mutual interest/60. Many dietary supplement grants that are inter-disciplinary do not fare well in existing study sections, and the ODS will work with the DRG to provide potential advisors knowledgeable about dietary supplements who can serve on review panels/61.

Sister Charlotte suggested that the ODS consider developing consumer-oriented teaching tools or self-instructional packets that provide guiding principles for evaluating information on dietary supplements/54. Mr. Hildenbrand stated that Congressional reform is needed to ensure that Federal funds are used for research which industry will not support because the substances under investigation cannot be patented/57. In addition, the large body of pre-World War II, university-level research on nutrition conducted in Europe should be assessed/56.

Dr. Jonas stated that encouraging empirical research is one of the OAM's major strategic issues, and is linked with other topics under discussion at the NIH regarding increasing support for clinical research in general. Because of overlap with ODS efforts, the OAM is de-emphasizing activities related to specific dietary supplements, mechanistic issues, and certain clinical issues/64-65. Significant overlap also exists between the OAM and the ODP in certain areas. With both Offices, the OAM is engaged in the strategic planning necessary to avoid duplication and maximize opportunities for collaboration/64,67-68.

IV. PRESENTATION AND DISCUSSION: OAM DIRECTOR'S REPORT
Dr. Wayne B. Jonas, Director, OAM

Dr. Jonas highlighted selected products, services, and activities of the OAM functional sections. (The AMPAC received briefing books containing summary functional section reports.)

EXTRAMURAL AFFAIRS

Coordination with the ICDs has proven to be extremely productive and is being increasingly emphasized. Using a six-step process, the OAM works with the ICDs to identify areas of mutual interest and activities most likely to yield activities meeting criteria discussed at the last AMPAC meeting for research efforts of practical relevance that can be accomplished in a reasonable time period/80-85. The involvement of OAM staff in intra-NIH and inter-ICD committee activities is essential to support collaboration between the OAM and ICDs/106-107,BB.

A midpoint review and update meeting with the Principal Investigators of the 10 CAM Research Centers cofunded by the OAM and various ICDs is scheduled for March 24-25, 1997/112,BB. Following are highlights of selected Center initiatives.

UC-Davis (asthma and immunology) has funded two grants examining the effects of orally administered wheatgrass juice on allergic rhinitis and asthma, and the role of self-administered acupuncture versus sham treatment on pulmonary function and quality of life among asthmatics. Other efforts include development of eight new research proposals, a technical assistance and education program, and a practitioner survey.

The University of Virginia (pain) has submitted 12 Research Opportunity Disposition Summaries (RODS). Two studies evaluate the effectiveness of chiropractic for TMJ and the diagnostic accuracy of subtle energy devices/102-103. Other efforts will assess the efficacy of post-operative massage for laparotomy patients and test the effects of binaural beat stimulation on EEG/102-103.

The Kessler Institute on Rehabilitation/University of Medicine and Dentistry-New Jersey (neurological disorders and stroke) has submitted 14 RODS on CAM treatments for stroke, spinal cord injury, and traumatic brain injury ranging from ginkgo biloba to neural reorganization therapy/103. The Kessler Institute will participate in a

consensus conference on traumatic brain injury organized by the NICHD with assistance from the OAM/103.

Columbia University (women's health) is performing qualitative research on ethnobotanical therapies for fibroids, endometriosis, hot flashes, and menorrhagia/103. A national survey on women's use of CAM is being developed.

Other research topics are Traditional Chinese Medicine (TCM) for uterine fibroids, mind/body interventions and herbal medicines for hot flashes, and Tibetan medicine for metastatic breast cancer/102-103.

The University of Texas (cancer) has identified 11 CAM therapies as priorities for evaluation including herbals (e.g., mistletoe), special regimens (e.g., the Gerson treatment program), organics/biologics (e.g., shark cartilage), and chemical/pharmacologics (e.g., antineoplastons)/104,BB. Prospective assessment appears to be appropriate for approximately five such treatments/104.

Harvard Medical School (general medicine) has conducted literature reviews on CAM therapies for low-back pain and ischemic heart disease/BB. Surveys are underway on the use of CAM therapies for ischemic heart disease, cancers, HIV, and postmenopausal hot flashes. Other surveys examine CAM use by persons with disabilities and by the Vietnamese community in Southern California/104-105,BB.

Hennepin County Medical Center (addiction) has completed an extensive review of CAM-related substance abuse literature that will be published as a book chapter in 1998/102,BB. A report on the first patient outcomes instrument for CAM has been submitted for publication/102,BB. Two surveys of physicians and members of the National Acupuncture Detoxification Association have been conducted/102,BB. Considerable technical assistance has been provided, and a research fellow is being funded/102,BB.

Bastyr University (HIV/AIDS) is continuing to prospectively monitor 1,500 HIV-positive individuals using CAM therapies and being tracked through a practice network established two years ago/105,206. A preliminary update report on 500 individuals followed for six months was presented at a meeting held at the CDC to introduce OAM activities and address research issues/105-206,BB.

The University of Maryland (pain) is developing a pilot longitudinal practice outcomes monitoring system, and several specialist surveys have been conducted/102,BB. A trial on chronic low-back pain and mind-body therapies has been completed/102,BB. Basic research is underway on

epidural modeling, antiemesis, and functional analgesic mechanisms of acupuncture/102,BB.

Stanford University (frailty in the elderly) has completed a survey on CAM insurance coverage, and is investigating the effects of nutritional therapy (e.g., soy diet) on estrogen parameters and cardiovascular risk factors/105. Other areas of focus are mind-body interventions, exercise and manipulation therapies, and combination therapies/BB.

RESEARCH DEVELOPMENT AND INVESTIGATION

The OAM continues to provide extensive, ongoing technical assistance in research methods, protocol development, grant proposal development, and practice assessments/BB. Ten additional practice assessments have been performed since the September 1996 AMPAC meeting; many practices may be appropriate for prospective evaluation with mechanisms currently in the planning phase/90-91,BB.

At the September 1996 meeting, Council assigned the highest priority to RFA and RFP development for more definitive research in clinical areas targeted by Council/68-69. Therefore, the OAM plans to allocate the additional \$4M allocated by Congress for fiscal year 1997 to four such projects outlined below/70-72,BB.

As discussed in previous AMPAC meetings, the POMES will provide a methodology and an infrastructure for systematically assessing CAM treatments for cancer/72,75. The POMES be a collaborative effort involving the OAM, the University of Texas Center for Alternative Medicine Research, and an as-yet-to-be-determined contract research organization/70,BB. A POMES planning conference cosponsored by the NCI has been tentatively scheduled for May 1997 to obtain recommendations from CAM practitioners, conventional oncologists, and researchers/70,111-112,BB.

In March 1997, the OAM anticipates issuing an RFA for a congressionally mandated Chiropractic Research Center/396,BB. The RFA will be cosponsored by other ICDs including the NIAMS through the U-24 cooperative agreement mechanism/70-71,396,417,BB. The Chiropractic Research Center will be the first CAM Research Center that is modality- and profession-focused rather than condition-focused/416.

With the NIMH and the ODS, the OAM is developing an RFP for a contract research organization to conduct a multicenter trial on hypericum (St. John's Wort) for treatment of depression/71-72,BB. With the NIAMS, the OAM also is

developing an RFA on acupuncture for osteoarthritic pain/72,397,BB. The OAM is temporarily placing on hold the study of EDTA chelation to treat cardiovascular disease due to an anticipated lack of funds in fiscal year 1997/397,BB.

INTERNATIONAL AND PROFESSIONAL LIAISON

OAM staff including Dr. Jonas, Dr. Carole Hudgings, and CAPT Nancy Hazleton traveled to Germany, China, and Singapore for activities related to development of collaborative relationships, practice assessments, and database exchange.

In Germany, Dr. Jonas met with a representative of the Federal Ministry for Education, Science, Research, and Technology (BMBF)/87; a BMBF representative will attend the midpoint review meeting of the OAM CAM Research Centers in March 1997. Dr. Jonas completed three hospital-based practice assessments/116. In addition, Dr. Carole Hudgings attended a conference on outcomes evaluation in CAM/86. In China, Dr. Jonas met with officials of the State Administration of Traditional Chinese Medicine and the WHO Collaborating Center in TCM, and with staff of TCM hospitals and research institutes/BB,87.

Thanks to the efforts of CAPT Hazleton, the OAM was designated a World Health Organization Collaborating Center in Traditional Medicine in October 1996/89,BB. The OAM has begun to assist in enhancing communication and coordination among the WHO Centers/89.

In Singapore, CAPT Hazleton met with Dr. S.T. Lee, Chief of Plastic Surgery at the Singapore General Hospital and reviewed data from his pilot study on MEBO ointment (a traditional Chinese remedy for burns)/149-150,BB. Dr. Lee will meet with the OAM in the United States in April/BB.

PUBLIC INFORMATION AND MEDIA RELATIONS

In October 1996, a five-year contract for the OAM Public Information Clearinghouse was awarded to a small business with more than 30 years' experience in clearinghouse operation/BB. The contractor has an extensive clearinghouse support infrastructure already in place and currently runs the National Institute of Aging's Alzheimer's clearinghouse/96-97. The new OAM Public Information Clearinghouse number is 1-888-NIH OCAM. Calls are answered live; information can be provided in English or Spanish, or through TDY lines for the hearing impaired/96-97,BB. Approximately 1,000 public information and media calls are received per month/BB. A draft cancer information packet currently is under review/BB.

DATABASE AND EVALUATION

In September 1996, a new contract was awarded for database and evaluation services/97,BB. The OAM Research Database and Internal CAM Research Library continue to be expanded and refined/BB. Work has begun on an annotated database of databases and on an annotated database of CAM journals/BB. Contract staff are being interviewed for the evidence-based CAM journal/BB. Standard Operating Procedures have been completed or are being prepared in areas including systematic reviews, exchange of citations between the CAM Research Centers and the OAM, database search requests, and translation/BB. Systematic reviews are underway in therapeutic touch, herbs, and direct mental influence/98.

While in Germany, Dr. Hudgings discussed database exchange and mechanisms for outcomes research with German research groups/BB,86,97. China maintains an online TCM database using the NLM's MeSH headings that will be extremely useful to the OAM; issues related to translation and the variable quality of the science need to be considered/87-88.

A meeting with the CDC was held in January 1997 to discuss areas of potential collaboration including survey research, outcomes research, and CAM-oriented training in epidemiological research/100. Similar meetings are planned with other Federal agencies including the AHCPR/99-100. Questions on CAM have been incorporated into many surveys with which the CDC is involved including National Health Surveys, the International Health Interview Survey, and the NHNES/99.

RESEARCH TRAINING

Work is continuing on the establishment of the Intramural Training Support Program Program/BB. The OAM will set aside sufficient funds for five three-year fellowships per year/108-109,BB. All intramural research labs and clinics at the NIH will be eligible to apply/107-108,BB. The OAM has begun to fund a clinical fellow with the NIAAA/395,107.

The OAM also funds research training through contributions to existing award programs/109,395,396.

OTHER ACTIVITIES

Development of a research prioritization process with the Institute of Medicine (IOM) was placed on hold/110. In accordance with the sentiments of many AMPAC members and after discussions with experts inside and outside the NIH, the decision was made that more strategic planning should be

accomplished by the OAM before an outside body such as the IOM is involved/110. After addressing strategic planning issues internally, the OAM will solicit recommendations from a larger group of advisors including representatives from the NIH and the AMPAC/110.

Approximately 20 developmental meetings and conferences are at various stages of planning or completion/10,397. Meetings have been held on CAM reimbursement, and on placebo effects in CAM and conventional medicine/111. Topics of forthcoming events include development of an international traditional medicine research agenda, African medicine, Islamic medicine, a systematic review of therapeutic touch, spirituality and prayer methodology, caring, and saw palmetto for benign prostatic hypertrophy/114.

FUTURE DIRECTIONS

Future areas of emphasis will include collaboration with the ICDs, management of the CAM Research Centers, RFA and RFP development, the POMES for CAM treatments in cancer, and developmental meetings and conferences. An additional long-term goal is the establishment of an adverse effects registry or ongoing monitoring system linked to a practice-based research system and coordinated with other surveillance mechanisms operated by the FDA and the CDC/114-116.

Dr. Jonas concluded his presentation by expressing special appreciation for the contributions of AMPAC members who will be rotating off Council, and for Dr. Gordon's guidance and leadership as AMPAC Chair/114.

During the ensuing discussion, Council addressed the following topics: Collaboration with the NCI, management of communication and conflict during the research process, practice assessments, investigation of phenomenal improvements, public information dissemination, selection of experts to validate CAM treatments, and followup research based on R21 results/117-119,123,124.

Dr. Moss remarked that many CAM treatments have been misevaluated and mishandled despite data clearly demonstrating their effectiveness/221,214. Dr. Jonas observed that trials must incorporate a system for managing the social aspects of research/124-125. A report on the OAM's analysis of the social aspects of the antineoplastons trial is under review, and some of the communication experts involved in that analysis will participate in the POMES planning conference/124-125,216.

Mr. Bedell stressed the need for more site visits and practice assessments to investigate CAM treatments for cancer/148-150,153-154,201-202. He stated that public information on treatments producing phenomenal improvements compared with conventional care should be disseminated if the improvements are documented to the OAM's satisfaction/151-152,165. Use of "phenomenal claims" as a possible prioritization criterion was discussed/158,161,173,175,179.

Dr. Temple remarked that miracles are infrequent in conventional drug development, and that a great deal of progress can be made by small increments/177-178.

Council agreed that more information on CAM treatments should be available to the public sooner, and the information must be readily understandable and properly contextualized/181-182. Communicating with the public only when all the data are available on a particular treatment may be preferable from a strictly scientific viewpoint, but individuals suffering from diseases such as pancreatic cancer cannot wait for the completion of lengthy studies; they must have access to preliminary information so that they can choose whether to investigate new treatments on their own/194, 181-182.

Drs. Jonas and Moss cautioned that the release of preliminary findings must be considered with great care to prevent harmful complications caused by factors such as treatment inaccessibility, marketing schemes, copycat treatments, and scams/194-197. Dr. Noreen Cavan Frisch suggested that a progress report be produced describing the OAM's past accomplishments and current initiatives/180.

Council agreed on the need for objective, neutral experts to validate CAM treatments for cancer; selection should be made especially quickly in areas with a clear natural history such as brain cancer and pancreatic cancer/204,205,192. Dr. Eisenberg recommended recruitment from sources outside the NIH; the CAM Research Centers might be able to identify appropriate experts/192. Ms. Burroughs suggested that coordination be increased between the R21s and Center research/180-181.

V. **PRESENTATION: USE OF HYPERICUM IN THE TREATMENT OF DEPRESSION**

Dr. Jerome Cott, Program Officer, NIMH

In collaboration with the OAM, the NIMH will conduct a multicenter trial to obtain definitive answers regarding the use of hypericum (St. John's Wort) for treatment of depression/248-250. The authors of a meta-analysis published in the *British Medical Journal* in 1996 conclude

that hypericum is an effective medication for mild and moderate depression, and recommend additional studies/238. Hypericum is approved for the treatment of depression in Germany, where it outsells all other antidepressants combined/231. Compared with standard antidepressants, the side-effects of hypericum are very minor/239.

Hypericum has been studied only for mild to moderate depression. There are no long-term studies, dose-finding studies, or studies with special populations such as the elderly or liver-impaired individuals. Interactions have not been specifically tested. No comparison trials have been conducted with an adequate dose of a comparison drug, and no studies have been performed in Europe comparing an active drug with a placebo in the same trial/239-241.

A standardized Hypericum preparation may be compared to a full therapeutic dose of an antidepressant popular in the United States, or both an active drug and a placebo may be included/241-243. Sample size will depend on the research questions/251. The study will be executed in the form of a contract/248-250. Dr. Cott stated that Dr. Temple's input on the study design would be greatly appreciated/257. A discussion followed Dr. Cott's presentation. Dr. Eisenberg suggested that the AMPAC consider reorienting Council priorities to incorporate the mental health area/246-247.

VI. DISCUSSION: OAM PRIORITIES AND STRATEGIC ISSUES

PROJECTED OAM BUDGET ALLOCATIONS

AMPAC members reviewed the fiscal year 1997 projected budget allocations/408,421-422?.

RESEARCH DEVELOPMENT AND INVESTIGATION

Mr. Hildenbrand suggested that "issues of cross-cutting importance," such as diagnostics and subtle energy, should be accorded highest priority/425,427. Dr. Beverly Rubik suggested that Congress be approached regarding the possibility of adding a significant prevention component to the OAM's mandate/412. Dr. Jonas noted that research on prevention (salutagenesis) is very costly and more difficult than research on recovery (self-healing processes); a center on recovery or healing would be more appropriate than a center on wellness/418-419.

Dr. Gordon recommended that consideration be given to funding research in self-care and in areas that particularly affect individuals underserved by virtue of race, economics, and age/450. Ms. Burroughs stated that a study of flower

essences, which are simple and inexpensive, could have an extremely powerful impact on mental health/441.

Dr. David Eisenberg suggested that a rapid deployment team be created of oncology experts outside the NIH community who would investigate CAM treatments which produce extraordinary results in patients with particularly serious cancers/427,249,433. Dr. Jonas noted that Council identified the need to involve experts at an earlier time in evaluating CAM practices to generate findings for public dissemination; the ECIS System (Extreme Cure Investigation Services) would function like a swat team that quickly moves into the field to investigate and report on dramatic effects/452-453.

Dr. Eisenberg recommended that a gift account be created to which the OAM and manufacturers of CAM products could contribute; the funds would be used to study the efficacy and safety of best-selling products that generate large profits for the manufacturers/429-431. Dr. Moss noted that the CAM Research Centers generally have the latitude to cooperate with manufacturers in such efforts/449. Dr. Cheung stated that the OAM has a gift fund to which donations can be made if there is no conflict of interest/444-445. Ms. Ellen Silverstone and Dr. Barrie Cassileth suggested that AMPAC members approach organizations such as pharmaceutical companies, herbal remedy companies, and foundations to explore their interest in supporting objective, independent research/445-449.

Dr. Eisenberg stated that clinical training programs should be created in medical schools and CAM provider schools for conventional and CAM practitioners who want to become bilingual in the dual cultures of CAM and conventional medicine so that they can knowledgeably communicate with patients regarding treatment options in both medicines/431-432.

PUBLIC INFORMATION

Topics included the need for the OAM Home Page and for the OAM to provide an information source on the Internet that is perceived to be reliable by all parties/436-438.

PROFESSIONAL LIAISON AND TRAINING

Sister Charlotte invited members of the legal community to consider themselves as wielders of treatments that support healing; legal issues are a source of stress for patients and practitioners/442.

Mrs. Marks stated that Council members should attend conferences in their own regions where CAM is discussed; work with hospitals, many of which are establishing CAM departments; and meet with medical students/371-372.

CENTER OR INSTITUTE STATUS

Council discussed potential advantages and disadvantages for the OAM of remaining a trans-NIH coordinating office versus achieving Center or Institute status/405-408,443. Dr. Jonas stated that neither the OAM nor the AMPAC can decide which situation would be preferable; the wider community of the public, the NIH, and Congress must be engaged in a dialog regarding the OAM's emphases and interests/455-456,459. The OAM's best posture is to invite open communication about creative ways of resolving the issue/456. Advantages of Center or Institute status include more autonomy and perhaps more resources/454-455. Disadvantages include more administrative activities, increased alienation from the community, and some loss of credibility as a valid information source/454-455,459.

VII. DISCUSSION: COUNCIL NOMINATIONS

The OAM submitted eight nominations to the Secretary, HHS, in mid-December 1996/332-333. Drs. Harlan and Cheung indicated that the terms of members scheduled to rotate off Council will be extended if some new members are not approved by the Secretary or if the Secretary's decisions are not received by the June 1997 meeting/333. Terms cannot be extended for one year at this time because the maximum number of Council members allowed by the Charter would be exceeded if new members are approved before the June 1997 meeting/336-337. The OAM has no control over how quickly nomination decisions are communicated from the Secretary/337.

Dr. Moss noted that the AMPAC is charged with representing the public's interests to the Administration, but no particular method exists for Council to provide input into member selection; if a clash occurs between the Administration and Council members, the nomination and rotation system enables the Administration, over time, to replace dissenting members with more malleable individuals/334-335. Dr. Harlan stated that the same nomination procedures are used for all NIH councils and include careful consideration of factors such as rotation off Council; nonconcurrent service on more than one council; and geographic, ethnic, and gender representation/336. The OAM maintains a file of approximately 170 potential Council members/337. All members of the AMPAC and the public are

welcome to submit nominations by providing a cover letter and a detailed resume to Dr. Cheung/337-338.

The OAM and Council expressed their appreciation for Dr. Gordon's immense contributions to Council, to the OAM, and to the CAM field/346. In line with the AMPAC Charter and the NIH-wide practice of appointing ICD directors as Council Chairs, Drs. Harlan and Cheung indicated that Dr. Jonas would succeed Dr. Gordon as OAM Chair/349. Dr. Cheung also observed that Council's advice is taken seriously, and mechanisms are in place up and down the chain of command through which the advice of advisory councils is heard/349-350. The chain of command retains the option of not taking all advice/350. Council stressed the uniqueness of the AMPAC and the OAM, and emphasized the need for a Chair independent of the OD who is able to serve as a neutral facilitator.

Based on a recommendation provided by Dr. Cassileth and amended by Council, Dr. Gordon moved that "a member of the Council be appointed [as] the next Chair ."/364 The motion passed with one opposed and no absentions/365. **[The number in favor was not repeated for the record.]**

VIII. CONSIDERATION OF MINUTES

Drs. Cheung and Gordon signed off on the minutes of the February 1997 AMPAC meeting. Dr. Cheung requested that AMPAC members submit any requests for modifications to him in writing for inclusion in the minutes of the next Council meeting as an amendment to the record.)

X. ADJOURNMENT

The eighth meeting of the AMPAC was adjourned at 1:00 p.m.* on February 11, 1997.

XI. APPENDICES

- A. AMPAC Meeting Agenda
- B. AMPAC Roster

NOTE: Open-session materials are available from the Executive Secretary or the Committee Management Officer.

XII. CERTIFICATIONS

We hereby certify that the foregoing minutes and supplements are accurate and complete to the best of our knowledge.

James S. Gordon, M.D.
Chair
Alternative Medicine Program
Advisory Council
and
Clinical Professor
Departments of Psychiatry and
Family Medicine
Georgetown University
and
Director
Center for Mind-Body Medicine

Date

Geoffrey P. Cheung, Ph.D.
Executive Secretary
Alternative Medicine Program
Advisory Council
Office of Alternative Medicine
National Institutes of Health

Date

Corrections or notations to these minutes will be incorporated into the minutes of the next AMPAC meeting.

APPENDIX A

AGENDA
EIGHTH MEETING
OF THE
ALTERNATIVE MEDICINE PROGRAM ADVISORY COUNCIL
Versailles I, Holiday Inn, Bethesda, Maryland
February 10-11, 1997

[Insert from briefing book.]

APPENDIX A

AGENDA (CONTINUED)

[Insert from briefing book.]

APPENDIX B
ROSTER
ALTERNATIVE MEDICINE PROGRAM ADVISORY COUNCIL
September 1996

[Insert from briefing book.]

APPENDIX B

ROSTER (CONTINUED)

[Insert from briefing book.]